



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEW
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 8 MARCH 2007

SUBJECT: **MYCLOBUTANIL** - Human, Non-Dietary Exposure/Risk Assessment for the Proposed New Uses of Myclobutanil On: Crop Group 8 (Except Tomato), Okra, Crop Subgroup 4A (Except Spinach), Cilantro, Artichoke, Papaya, Black Sapote, Mamey Sapote, Canistel, Mango, Sapodilla and Star Apple

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INTRODUCTION

Under provisions in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, the Inter-Regional Research Project Number 4 (IR 4) and the Dow AgroSciences company have requested registration for use of the fungicide myclobutanil on Crop Group 8 (except tomato), which includes but not limited to pepper (Bell and non-Bell), eggplant and okra. The request includes use on Crop Group 4A (except spinach) which includes amaranth, arugula, chervil, garland chrysanthemum, corn salad, garden cress, upland cress, dandelion, dock, endive, lettuce, orach, parsley, garden purslane, winter purslane, radicchio (red and chicory) and cilantro. Registration is also requested for artichoke, papaya, black sapote, mamey sapote, canistel, mango, sapodilla and star apple.

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This memorandum serves as the RD's assessment of exposure and risk to occupational pesticide handlers (mixers, loaders, applicators) and to agricultural workers. It should be noted that the risk assessment techniques used in this document are those that have been developed and refined by the Health Effects Division (HED)/Office of Pesticide Programs' Science Policy Council for Exposure (ExpoSAC). Therefore, the risk assessment methods are the same as those used by HED and are HED standard operating procedure (SOP).

USE PATTERN SUMMARY

The use pattern summary is taken primarily from the Sections B of the IR 4 submissions and from supplemental labeling. Rally[®] 40 W (Reg. No. 62719 - 410) is the registered product for which amendment is requested. Rally[®] is formulated as a 40 % by weight active ingredient (ai) wettable powder. Rally[®] 40 W is actually Rally[®] 40 WSP. Rally[®] 40 WSP is packaged in water soluble packaging which is an important factor related to mixer/loader exposure assessment.

For the Crop Group 8 and Crop SubGroup 4A, the IR 4 submission lists an alternate product, Nova[®] 40 W (Reg. No. 62719 - 411). According to the OPPs OPPIN Summary Information for Product Registration - Section 3, the product associated with Reg. No. 62719 - 411 is Systhane[®], a cotton seed treatment product. Nova[®], at one time, was evidently similar to Rally[®] and ARIA/RIMUERB is considering them as the same. The IR-4 appears to consider the two products interchangeably.

The Rally[®] product label requires applicators and other handlers to wear personal protective equipment (PPE) consisting of: long-sleeved shirt, long pants, chemical resistant gloves (Category A in EPA's chemical resistant category selection chart), shoes plus socks and protective eyewear. The label lists a 24-hour restricted entry interval (REI).

Crop Group 8 (except tomato), peppers, eggplant and okra. Crop Subgroup 4A (except spinach).

The target pest is powdery mildew. The rate of application ranges from 2.5 oz - 5.0 oz product/A (0.0625 - 0.125 lb ai/A). Applications are to be foliar and should use the lower rates for small plants and higher rates as plant increase in size. There is a maximum of 1.25 lb product/A/growing season (0.5 lb ai/A/season) which equates to 4 applications at the highest rate. The application interval is 10 -14 days. For Crop Group 8, applications may be made up to and including the day of harvest. For Crop SubGroup 4A, there is a 3 day preharvest interval (PHI). According to the supplemental labeling submitted by Dow, use on Crop Group 8 is limited to use in Arizona, California and Hawaii. Use on okra is limited to California. Applications are expected to primarily be applied by ground-boom spray equipment and to lesser extent aerially or through irrigation systems (*i.e.*, chemigation).

Artichoke

For artichoke the rate of application ranges from 3.0 - 4.0 oz/A (0.075 - 0.1 lb ai/A) and the target pest is powdery mildew. Applications are to be foliar or as a bud spray with the lower rates applied to small plants and the higher rate to larger plants. There is a maximum of 0.6 lb ai/A/season. There may be 6 applications/season at the high rate. The application interval is 14 days. The PHI is 3 days. According to the supplemental labeling, use on artichoke is limited to Arizona, California and Hawaii. Applications are most likely to be by a modified ground boom or some type of air assisted spray. Aerial applications or chemigation are also possible.

Tropical fruit (papaya, sapote, canistel, mango, sapodilla, star apple)

Applications are to be foliar at a maximum rate of 0.25 lb ai/A for powdery mildew. There is a maximum of 2.0 lb ai/A/season which equates to 8 applications/A/season. The application interval is 14 days. The supplemental label indicates use is limited to Arizona, California and Hawaii. The tropical fruits are most likely treated with some type of air-blast equipment.

See Table 1.0 for a summary of the proposed use pattern.

Table 1.0 Summary of Proposed New Use Pattern for Myclobutanil	
Crop/Site	Crop Group 8 Crop Subgroup 4A Artichoke Tropical fruit
Pest	Powdery mildew
Method of Applic.	ground boom, airblast, aerial, chemigation
Max. Applic. Rate	Crop Group 8 and Crop Subgroup 4A 0.125 lb ai/A Artichoke 0.1 lb ai/A Tropical fruit 0.25 lb ai/A
Max. No. Applications	Crop Group 8 and Crop Subgroup 4A 4/season Artichoke 6/season Tropical fruit 8/season
Applic. Interval	Crop Group 8 and Crop Subgroup 4A 10 - 14 days Artichoke 14 days Tropical fruit 14 days
Preharvest Interval	Crop Group 8 = 0 days Crop Subgroup 4A 3 days Artichoke 3 days Tropical fruit 0 days
Restricted Entry Interval	24 hours
Manufacturer	Dow AgroSciences

OCCUPATIONAL PESTICIDE HANDLER EXPOSURE

Based upon the proposed new use patterns, RD believes the most likely methods of application are likely to be by ground boom and by airblast. The Rally[®] "parent" (i.e., not supplemental labels) label indicates that chemigation and aerial applications are permitted.

RD expects the most highly exposed occupational handlers would most likely be mixer/loaders loading wettable powder packaged in water soluble packaging, applicators using open-cab ground-boom and open-cab airblast spray machinery and aerial applicators.

Persons involved in chemigation are not formally assessed. There is no "applicator" *per se* for applications through irrigation systems. An occupational handler would be responsible for preparing a concentrate solution from which pesticide is "metered" into the irrigation system water. As such, the handler is essentially performing similar tasks to a mixer/loader preparing solution for application by aircraft or by ground machinery. RD believes a handler preparing for application through irrigation machinery would not be more highly exposed than a mixer/loader supporting aerial operations.

Since the treatment blocks (i.e., areas treated) are relatively small for the proposed new crop uses (as compared to typical field crops such as cotton, corn, soybeans or wheat), RD believes pesticide handlers will be exposed to short-term duration (1 - 30 days) exposures but not to intermediate-term (1 - 6 months) duration exposures. However, since multiple applications are permitted, it is possible that commercial applicators might experience intermediate-term duration exposures. Risks are estimated for short-term and intermediate-term duration exposures.

Particularly for ground applications, private (i.e., grower) applicators may perform all functions, that is, mix, load and apply the material. The HED ExpoSAC SOP Number 12 (29 March 2000) directs that although the same individual may perform all those tasks, they shall be assessed separately. The available exposure data for combined mixer/loader/applicator scenarios are limited in comparison to the monitoring of these two activities separately. These exposure scenarios are outlined in the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (August 1998). HED has adopted a methodology to present the exposure and risk estimates separately for the job functions in some scenarios and to present them as combined in other cases. Most exposure scenarios for hand-held equipment (such as hand wands, backpack sprayers, and push-type granular spreaders) are assessed as a combined job function. With these types of hand held operations, all handling activities are assumed to be conducted by the same individual. The available monitoring data support this and HED presents them in this way. Conversely, for equipment types such as fixed-wing aircraft, groundboom tractors, or air-blast sprayers, the applicator exposures are assessed and presented separately from those of the mixers and loaders. By separating the two job functions, HED determines the most appropriate levels of personal protective equipment (PPE) for each aspect of the job without requiring an applicator to wear unnecessary PPE that might

be required for a mixer/loader (e.g., chemical resistant gloves may only be necessary during the pouring of a liquid formulation).

No chemical specific data were available with which to assess potential exposure to pesticide handlers. The estimates of exposure to pesticide handlers are based upon surrogate study data available in the PHED (v. 1.1, 1998). For pesticide handlers, it is HED standard practice to present estimates of dermal exposure for "baseline" that is, for workers wearing a single layer of work clothing consisting of a long sleeved shirt, long pants, shoes plus socks and no protective gloves as well as for "baseline" **and the use of protective gloves** or other PPE as might be necessary.

On 12 August 1999 the HED Hazard Identification Assessment Review Committee (HIARC) met to discuss the adequacy of the toxicological database relative to myclobutanil (Memo, M. Copley, HED DOC NO 013740, "**MYCLOBUTANIL** - Second Report of the Hazard Identification Assessment Review Committee", 2 September 1999). Subsequently, the RAB1 toxicologists re-evaluated the myclobutanil toxicology database and concluded that the 28-day dermal toxicity study previously used for short-term dermal risk assessment was not appropriate. A two-generation reproduction study in rats was selected. With regards to the assessment herein, the short-term duration (1 - 30 days) and the intermediate-term duration (1 - 6 months) dermal and inhalation toxicological endpoints are identified from a 2- generation reproduction toxicity study in the rat. The NOAEL is 10.0 mg ai/kg bw/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation. The HIARC identified a 50 % dermal absorption factor for use in assessing dermal exposures. The RAB 1 toxicology team cited the same study for the inhalation endpoint, noting the same effects and NOAEL. Inhalation absorption is assumed to be 100 %. The intermediate-term dermal and inhalation NOAELs are the same as those noted for short-term duration exposures and are cited from the same 2-generation rat reproduction study. See Table 2.0 for a summary of exposures and risks to occupational pesticide handlers. See the ATTACHMENT for a summary of the toxicological endpoints used for risk assessment.

Table 2.0 Summary of Exposure & Risk for Occupational Handlers Applying Myclobutanil				
Unit Exposure¹ mg ai/lb handled	Applic. Rate² lb ai/unit	Units Treated³	Avg. Daily Exposure⁴ mg ai/kg bw/day	MOE⁵
<i>Mixer/Loader Using WP in Water Soluble Packaging (in support of aerial operations)</i>				
Dermal: SLNoGlove 0.021 LC SLWithGlove 0.0098 LC Inhal. 0.00024 LC	0.25	350	Dermal: SLNoGlove 0.013 SLWithGlove 0.00613 Inhal. 0.0003	No Glove 752 With Glove 1,555
<i>Applicator - Groundboom Open-Cab</i>				
Dermal: SLNoGlove 0.014 HC SLWithGlove 0.014 MC Inhal. 0.00074 HC	0.125	200	Dermal: SLNoGlove 0.0025 SLWithGlove 0.0025 Inhal. 0.000264	No Glove 3,617 With Glove 3,617
<i>Applicator - Airblast Open-Cab</i>				
Dermal: SLNoGlove 0.36 HC SLWithGlove 0.24 HC Inhal. 0.0045 HC	0.25	40	Dermal: SLNoGlove 0.0257 SLWithGlove 0.017 Inhal. 0.000643	No Glove 380 With Glove 567
<i>Aerial Applicator</i>				
Dermal: SLNoGlove 0.0050 MC Inhal. 0.000068 MC	0.25	350	Dermal: SLNoGlove 0.00313 Inhal. 0.000085	No Glove 3,110

1. Unit Exposures are taken from "PHED SURROGATE EXPOSURE GUIDE", Estimates of Worker Exposure from The Pesticide Handler Exposure Database Version 1.1, August 1998. Inhal. = Inhalation. Units = mg a.i./pound of active ingredient handled. Data Confidence: LC = Low Confidence, MC = Medium Confidence, HC = High Confidence.

2. Applic. Rate. = Taken from the IR 4 submission Sections B

3. Units Treated are taken from "Standard Values for Daily Acres Treated in Agriculture"; SOP No. 9.1. Science Advisory Council for Exposure: Revised 5 July 2000;

4. Average Daily Dose (ADD) = Unit Exposure * Applic. Rate * Units Treated * absorption factor (50% dermal) ÷ Body Weight 70 kg.

5. NOAEL = No Observable Adverse Effect Level (10 mg a.i./kg bw/day for short-term and intermediate-term dermal and inhalation)

6. MOE = Margin of Exposure = No Observable Adverse Effect Level (NOAEL = 10 mg ai/kg bw/day) ÷ ADD. The ADD = dermal exposure + inhalation exposure.

A MOE of 100 is adequate to protect occupational pesticide handlers from exposures to myclobutanil. All MOEs are > 100 therefore the proposed uses do not exceed RDs level of concern.

POST-APPLICATION EXPOSURE TO AGRICULTURAL WORKERS

It is possible for agricultural workers to have post-application exposures to pesticide residues during the course of typical agricultural activities. HED in conjunction with the Agricultural Re-entry Task Force (ARTF) has identified a number of post-application agricultural activities that may occur and which may result in post-application exposures to pesticide residues. HED has also identified Transfer Coefficients (TC) (cm²/hr)

relative to the various activities which express the amount of foliar contact over time, during each of the activities identified.

For the proposed new crop use sites, the highest TC for fruiting vegetables and artichoke is 1,000 cm²/hr for hand harvesting. The highest TC for root vegetables and for greens is 2,500 cm²/hr for hand harvesting. Tropical fruit are not named specifically in the database. However, RD assumes there would not be significant difference from the highest TCs for hand harvesting citrus or pome or stone fruit (which is 3,000 cm²/hr). Therefore, as a "screening" level assessment, RD herein uses a TC of 3,000 cm²/hr.

The TCs used in this assessment are from an interim TC Standard Operating Procedure (SOP) developed by HED's ExpoSAC using proprietary data from the ARTF database (SOP # 3.1). It is the intention of HED's ExpoSAC that this SOP will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from further analysis of studies already submitted to the Agency, and from studies in the published scientific literature.

Lacking compound specific dislodgeable foliar residue (DFR) data, HED assumes 20 % of the application rate is available as DFR on day zero after application. This is adapted from the ExpoSAC SOP No. 003 (7 May 1998 - Revised 7 August 2000).

The following convention may be used to estimate post-application exposure.

Average Daily Dose (ADD) (mg a.i./kg bw/day) = DFR μg/cm² * TC cm²/hr * hr/day * 0.001 mg/μg * 1/70 kg bw

and where:

Surrogate Dislodgeable Foliar Residue (DFR) = application rate * 20% available as dislodgeable residue * (1-D)^t * 4.54 x 10⁸ μg/lb * 2.47 x 10⁻⁸ A/cm².

0.25 lb a.i./A * 0.20 * (1-0)⁰ * 4.54 x 10⁸ μg/lb * 2.47 x 10⁻⁸ A/cm² = 0.56 μg/cm², therefore,

0.56 μg/cm² * 3,000 cm²/hr * 8 hr/day * 0.001 mg/μg * 0.50 (% dermal absorption) ÷ 70 kg bw = 0.096 mg/kg bw/day.

MOE = NOAEL ÷ ADD then 10.0 mg/kg bw/day ÷ 0.096 mg/kg bw/day = 104.

A MOE of 100 is adequate to protect agricultural workers from post-application exposures. Since the estimated MOEs are > 100, the proposed uses do not exceed RD's level of concern.

RESTRICTED ENTRY INTERVAL (REI)

Myclobutanil is classified in Acute Toxicity Category I for primary eye irritation and in Acute Toxicity Category IV for acute dermal toxicity, acute inhalation toxicity and primary skin irritation. It is a dermal sensitizer. The labels list a 24 hour REI.

Title 40 of the Code of Federal Regulations, § 156.208 (c) (2) states: If a product contains only one active ingredient and it is in Toxicity Category I by the criteria in paragraph (c) (1) of this section, the restricted-entry interval shall be 48 hours.” The Federal Register Vol. 57, No. 163, 21 August 1992 page 38104 and 38142 (For 40 CFR Parts 156 and 170) indicates that “...a 48-hour REI is established for any product containing an active ingredient that is in toxicity category I (most acutely toxic category) because of dermal toxicity or skin or eye irritation.”

The 24 hour REI listed on the product labels should be confirmed or corrected as may be necessary.

ATTACHMENT

Acute Toxicity of Myclobutanil

Guideline No.	Study Type	MRID #(S)	Results	Toxicity Category
81-1	Acute Oral	00141662	LD ₅₀ = 1.6 g/kg (M) LD ₅₀ = 2.29 g/kg (F)	III
81-2	Acute Dermal	00141663	LD ₅₀ > 5000 mg/kg	IV
81-3	Acute Inhalation	40357101	LC ₅₀ > 5.1 m/L	IV
81-4	Primary Eye Irritation	00141663	Severe eye irritant	I
81-5	Primary Skin Irritation	00141663	Non-irritating to skin	IV
81-6	Dermal Sensitization	40357102	Positive sensitizer	

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary <u>females 13-50 years of age</u>	NOAEL=60 UF = 100	LOAEL = 200 mg/kg/day based on increased resorptions, decreased litter size and a decrease in the viability index.	Developmental Toxicity - rabbit
	Acute RfD = 0.60		
Acute Dietary <u>general population including infants and children</u>	none		
	Acute RfD = none		
Chronic Dietary	NOAEL = 2.49 mg/kg/day UF = 100	LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy.	Chronic Toxicity/ Carcinogenicity - rat
	Chronic RfD = 0.025 mg/kg/day		
Short-Term (Dermal)	oral NOAEL=10 mg/kg/day ¹	LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.	2 Generation Reproduction Toxicity - rat
Intermediate-Term (Dermal)	oral NOAEL=10 mg/kg/day ¹	LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.	2 Generation Reproduction Toxicity - rat
Long-Term (Dermal)	oral NOAEL = 2.49 mg/kg/day ¹	LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy.	Chronic Toxicity/ Carcinogenicity - rat
Short Term	oral	LOAEL = 50 mg/kg/day based on atrophy of the testes	2 Generation

(Inhalation)	NOAEL=10 mg/kg/day ²	and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.	Reproduction Toxicity - rat
Intermediate Term (Inhalation)	oral NOAEL=10 mg/kg/day ²	LOAEL = 50 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborn pups and a decrease in pup weight gain during lactation.	2 Generation Reproduction Toxicity - rat
Long Term (Inhalation)	oral NOAEL =2.49 mg/kg/day ²	LOAEL = 10 mg/kg/day based on decreased testicular weights and increased testicular atrophy.	Chronic Toxicity/ Carcinogenicity - rat

¹ Use the appropriate dermal absorption factor (50%) since the NOAEL is from an oral study.

² Use the appropriate absorption factor (100%) since the NOAEL is from an oral study.

NOTE: ATTACHMENT taken from: Memo, M. Copley, "**MYCLOBUTANIL**: - Second Report of the Hazard Identification Assessment Review Committee", HED DOC NO 013740, 2 SEPT 1999 **and amended by the RAB1 toxicology team.**

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OPP OFFICIAL RECORD
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Cacodylic Acid, Quantitative Risk Assessment, Two-
Year Charles River (F344) Rat
Dietary Study

Caswell no.133

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Summary

The unit risk, Q_1^* of Cacodylic Acid, based upon male and female rat urinary bladder transitional cell (papillomas and/or carcinomas) tumors is 6.23×10^{-2} (mg/kg/day)⁻¹ in human equivalents. The dose levels used in this 2-year study were 0, 2, 10, 40 and 100 ppm. of Cacodylic Acid. The proportions of urinary bladder tumors observed in the rats (male & female) were 0/119, 1/118, 1/116, 1/113 and 12/113 for the above mentioned respective dose levels.

Background

In December, 1993, the Peer Review Committee recommended that a quantitative risk assessment for Cacodylic Acid be estimated from urinary bladder transitional cell (papillomas and/or carcinomas) tumor rates in female rats and in both sexes combined.



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The statistical evaluation (Cacodylic Acid Qualitative Risk Assessment-Charles River Fischer F344 Rat Dietary Study, L.Brunsmann 11/93) indicated no significant increasing mortality with dose increments of Cacodylic Acid in either male or female rats.

Female rats had dose related a significantly increasing trend ($p=.00$) in urinary bladder transitional cell (papillomas and/or carcinomas) tumor rates (0/59, 0/59, 0/57, 0/56 and 10/58) with dose increments of Cacodylic Acid. Male rats also had increasing incidence of urinary bladder transitional (papillomas and/or carcinomas) tumor rates (0/60, 1/59, 1/59, 1/57 and 2/55) but did not have a statistically significant trend ($p=.11$). The combined incidence of urinary bladder transitional cell (papillomas and/or carcinomas) for both sexes was 0/119, 1/118, 1/116, 1/113 and 12/113 for dose levels of 0, 2, 10, 40 and 100 ppm of Cacodylic Acid.

Dose-Response

Since mortality was not significantly increased by incremental doses of Cacodylic Acid in either sex, the estimate of the unit risk, Q_1^* in human equivalents was obtained by the application of the Multi-Stage model (Tox_Risk program, version 3.5- K.Crump). The conversion to human equivalents was made by the use of the 3/4's scaling factor*. An estimate of risk, Q_1^* , was calculated for the females and for both sexes combined from urinary bladder transitional cell (papillomas and/or carcinomas) tumor rates.

The result of the estimate of unit risk, Q_1^* is as follows:		
Species, strain	tumor:	Q_1^* (mg/kg/day) ⁻¹
Rat: Charles River, Fischer f344	urinary bladder transitional cell (papillomas & ca.)	in Human Equivalents
Female		3.65×10^{-2}
Both sexes		6.23×10^{-2}

It is to be noted that Q_1^* (mg/kg/day)⁻¹ is an estimate of the upper bound (95%) on risk and that (as stated in the EPA Risk Assessment Guidelines) "the true value of the risk is unknown, and may be as low as zero."

* See Memo - Deriving Q_1^* s Using the Unified Interspecies Scaling Factors, P.A. Fenner-Crisp, Director-HED, 7/1/94.

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Caswell File



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Chemical: Myclobutanil

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